

Remarks

Claims 1, 3-4, 6-15, 17, and 19-20 are presented for the Examiner's review and consideration. In this response, claims 1, 4, 6, 8 14-15, 17 and 19-20 are amended, and claims 2, 5, 16 and 18 are cancelled. Applicant believes the accompanying remarks herein serve to clarify the present invention and are independent of patentability. No new matter has been added.

Objections to the Drawings

The drawings were objected to under 37 C.F.R. §1.83(a) as not showing every feature of the invention specified in the claims, and particularly with respect to claims 2, 14, 16, 18 and 20. Initially, Applicant notes that claims 2, 16 and 18 are cancelled.

Claims 14 and 20 have been amended accordingly. In addition, replacement drawings are submitted, herewith. No new matter has been added. Applicant therefore respectfully submits that this objection should be withdrawn.

Objection to the Title

The title was objected to as not being clearly indicative of the invention to which the claims are directed. In response, a new title is submitted, herein. No new matter has been added. Accordingly, Applicant respectfully requests that the objection be withdrawn.

Objections to the Specification

The specification was objected to because Fig. 4a was not described in the specification. In response, Applicant has removed Fig. 4a from the replacement drawings, provided herein. Accordingly, Applicant respectfully requests that the objection be withdrawn.

Rejections under 35 U.S.C. §112

Claims 1-20 were rejected under 35 U.S.C. §112, first paragraph, for failing to comply with the written description requirement.

The Examiner has mentioned that the following claimed terms are not mentioned in the specifications: "any configuration of electrode positioning may be attained"; mounting of

elements "directly or indirectly"; "moving/adjusting of various holders"; "actuators/activating means" and "electrical/hydraulic or manual".

1. "any configuration of electrode positioning may be attained" has been erased from claim 1.
2. "directly or indirectly" as well as the actuating means are mentioned in the specifications paragraph [0011] "The present invention thus consists in an electrode positioning device (as herein defined) which consists in a base which is to be connected to the brain directly or indirectly using a remote adapter, on said base being mounted directly or indirectly movable terminal holders on which holders extend guides, on which guides extend movable means which means hold the guiding tubes (as well called tubes) and the electrodes, said electrodes being actuated by suitable actuating means."
3. The term "activating means" in the claims is amended and replaced by the term "actuating means".
4. "adjusting of various holders" is not mentioned in the claims.
5. The "electrical/hydraulic or manual" actuating means are mentioned in paragraph [0024] "the actuating means in the Z direction may be electrical ones, e.g. a motor; hydraulic ones and even manual ones".

The Examiner mentioned other terms such as "head" and electrode" or "electrode guiding" and claimed they lack clear and proper antecedent basis.

The Applicant asserts that these terms are known in the art and are commonly used by ones of ordinary skills in the art and that the drawings explain most of these terms, such as, for example: electrode, terminal, tube, electrode guide etc.

The Applicant respectfully asserts that the amendments to the claims and the above clarifications show that the Application does comply with the requirements of 35 U.S.C. §112 first and second paragraphs.

In light of the foregoing, Applicant respectfully requests reconsideration and withdrawal of the Section 112 rejections.

Rejections under 35 U.S.C. §102

Claims 1-20 were rejected under 35 U.S.C. §102(e) as being anticipated by Arambula et al. (U.S. 7,166,113) ("Arambula"), and under §102(b) as being anticipated by Day et al. (U.S. 5,891,157) ("Day"). For reasons set forth below, Applicant respectfully submits that these rejections should be withdrawn.

Arambula teaches:

"A surgical instrument positioning system, comprising: at least one support; a cross member having at least one curved end portion, the at least one curved end portion being held by the at least one support such that the cross member is rotatable about an axis extending through a center of curvature of the at least one curved end portion of the cross member; and at least one surgical instrument holder suspended from the cross member. A laser alignment system for an image intensifier, comprising: at least one laser source which emits planar laser beams in first and second intersecting planes." [Abstract]

Arambula teaches a positioning system that has a curved cross member upon which the surgical instruments (e.g. electrodes) are mounted the entire cross member (illustrated in Arambula's application as an arched frame) can rotate around the patient's head once the supports are affixed to the patient's head.

This may not allow completely individual and independent positioning of each surgical instrument separately. The instruments may only move according to the curve of the cross member only allowing the user (e.g. the surgeon) to set the distances between the instruments along the curve of the cross member. Therefore Arambula's system is not designed for positioning a multiplicity of instruments where each can be independently positioned in XY and Z axes while affixing the cross member (which can be compared to the Applicant's base).

Many other prior art cited by the Examiner such as:

US6,416,520B1; US6,423,077B1; US6,413,263 B1; US7,033,326B1;US4,608,977 A; US4,638,798 A; US5,649,936 A; and US5,817,106 A, share the same or some of the positioning directional properties and limitations of Arambula's system.

Day teaches:

"A non invasive apparatus for supporting tools associated with a stereotactic apparatus and procedures to guide tools along any selected path. In one embodiment of the invention, the tool support system is mounted to a skull clamp holding a patient's head .." [Abstract]

"... tooling support system 16 that couples the articulated arm and probe 18 to the patient to permit surgical path evaluation and selection. A support apparatus preferably a halo-style annular retractor... A tool holder including an alignment ball and socket mount 92 has a block 94 that is mounted in the slots 90 of retractor support 78. The block 94 further supports a ring 96 on which an alignment element preferably an alignment ball 98 and socket 100 are mounted. The alignment ball 98 has a bore 103 shaped to receive the end of the probe 24. Thus, the probe 24 is inserted into the alignment ball 98, and the probe 24 and ball 98 are moved and rotated together with respect to the patient's head 13.

Once a particular orientation has been selected by the surgeon based upon information provided by the radiological image displayed on monitor 32, the screws 102 extending through the socket 100 are tightened to form a clamp that secures the alignment ball 98 in place. A surgical instrument collar of known type (not shown) may then be inserted within the bore 103 of the alignment ball 98 to permit a drill or other instrument 105 (shown in phantom) to be inserted through the instrument collar to open the patient's skull. A biopsy instrument may also be inserted through the collar to the target area. Thus, using the tooling support system 16 illustrated in FIG. 1, stereotactic surgical procedures are performed without the use of an invasive skull ring. In addition, using the known retractor

support ring 78, the alignment ball 98 and socket 100 may be located over any desired area of the skull. Further, since the retractor support 78 has two lateral supports, 84, 86, 88, it provides a rigid and stable support for the alignment ball 98 and surgical instruments inserted therethrough, thereby minimizing the potential of the position and/or orientation of the alignment ball 98 changing with respect to the patient's head 13." [Description]

According to Day, only one tool holder can guide the probe finger, where the probe finger is manually inserted by the surgeon that can view the positioning through the screen. To allow placing and positioning a multiplicity of probe fingers – a multiplicity of tool holders should be mounted to the apparatus.

Moreover, Day does not teach of other holding elements attached to the tool holder that allow tilting the finger in relation to the tool holder.

Additionally, once the surgeon fastens the probe finger to the tool holder the finger is affixed in the Z axis, which is perpendicular to the XY plane defined by the annular support. Day does not allow rotational movement enabling to rotate the finger around the Z axis. This may limit the surgeon when fine positioning adjustments are required.

The Applicant teaches a device that allows the user to work with a multi-channel system with the possibility "to position each electrode or group of electrodes in the XYZ planes individually and independently". (Paragraph [0015]).

According to the Applicant, the base is substantially a circular frame that can be mounted on a patient's head where a multiplicity of terminals comprising terminal holders that can hold terminals, where the terminals can hold one or more electrodes.

" The terminals may be arranged in various positions, each being distanced differently from the center of the base and individually being located in the XYZ plane." (Paragraph [0023])

The Applicant's terminal holders are positioned along the curved circumference of the base, where each holder is directed radially and inwardly towards the center of the circle of the base. The terminals can be moved radially along the XY plane defined by the base. Additionally, each terminal may comprise one or more electrode holders (see Paragraphs [0041-0042]) which are mounted along the terminal. The terminals are elongated elements which are positioned substantially perpendicularly to the XY plane defined by the base. The electrode holders may further allow moving the electrode along a Z axis defined by the terminal, which is perpendicular to the XY plane defined by the base as well as tilting of the electrode in relation to the terminal and rotatably move the electrode around the Z axis defined by the terminal. This allows many directions and positions in the X, Y, and Z axes where the electrode that is held by the electrode holder can be moved to allow a user (such as a physician) to position each electrode individually and independently in a fine manner involving many degrees of freedom. This may be extremely crucial and important when it comes to analyzing brain cells electric activity, for example, in brain surgeon.

Moreover, the Applicant's device allows holding a large number of terminals and electrodes and optimizing the distances between adjacent electrodes (see Figures 7-9) such as minimizing the distances between adjacent electrodes allowing inspecting and analyzing a larger area of the patient's brain and obtaining finer resolutions.

Positioning a multiplicity of terminals is not oblivious and requires a complicated design to enable freedom of operation to place each terminal and each electrode held by the terminal in any XYZ position. Allowing this independent positioning of each electrode can be a crucial factor when conducting a complicated surgery that requires electrode positioning (such as a neurosurgery).

None of the patents and applications cited by the Examiner allows these many and specific movement directions as the ones taught by the Applicant. Moreover, none of the prior art citations specifically addresses the issue of or allows mounting a large number of electrodes

onto the same base while enabling individually and independent positioning adjusting each of the mounted electrodes in one of the possible: (i) rotational movement along the circumferential curve of the base (XY plane defined by the base); (ii) radial movement along the terminal holder (XY plane); (iii) longitudinal movement that is substantially perpendicular to the XY plane defined by the base (Z axis) along the terminal; (iv) rotational movement around the axis defined by the terminal (around the Z axis); and other tilting movements enabled by the electrode holders. All movement possibilities enabling independently moving each electrode along one or more X, Y, and Z axes.

In light of the foregoing, Applicant requests reconsideration and withdrawal of the section 102 rejections.

Conclusion

In light of the foregoing remarks, this application is now in condition for allowance and early passage of this case to issue is respectfully requested.

If any questions remain regarding this amendment or the application in general, a telephone call to the undersigned would be appreciated since this should expedite the prosecution of the application for all concerned.

No fees are believed to be due. However, please charge any other required fee (or credit overpayments) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 7044-X07-139).

Respectfully submitted,

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